

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION

*THIS DOCUMENT RELATES TO:*

COUNTY OF SUFFOLK,

Plaintiff,

v.

ABBOTT LABORATORIES, INC., AGOURON  
PHARMACEUTICALS, INC., AMGEN, INC.,  
ASTRAZENECA PHARMACEUTICALS L.P.,  
ASTRAZENECA US, AVENTIS BEHRING,  
AVENTIS PHARMACEUTICALS INC., BARR  
LABORATORIES, INC., BAYER AG, BERLEX  
LABORATORIES, INC., BIOGEN, INC., BRISTOL  
MYERS SQUIBB COMPANY, ELI LILLY AND  
COMPANY, FUJISAWA PHARMACEUTICAL  
COMPANY, LTD., GENENTECH, INC., GLAXO  
WELLCOME, P.L.C., GLAXOSMITHKLINE PLC,  
IMMUNEX CORPORATION, IVAX  
CORPORATION, IVAX PHARMACEUTICALS  
INC., JANSSEN PHARMACEUTICAL, JOHNSON &  
JOHNSON, MEDIMMUNE, INC., MERCK & CO.,  
INC., NOVARTIS PHARMACEUTICALS  
CORPORATION, ORTHO BIOTECH, ORTHO  
MCNEIL PHARMACEUTICALS, PFIZER INC.,  
PHARMACIA CORPORATION, PURDUE  
PHARMA, L.P., RELIANT PHARMACEUTICALS,  
SANOFI-SYNTHELABO, INC., SCHERING-  
PLOUGH CORP., SMITHKLINEBEECHAM P.L.C.,  
TAP PHARMACEUTICALS, WARRICK  
PHARMACEUTICALS, WYETH, AND DOES 1-100,

Defendants.

MDL NO. 1456

C.A. No. 01-CV-12257 (PBS)

HON. PATTI B. SARIS

**CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'  
MOTION TO DISMISS THE AMENDED COMPLAINT**

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Preliminary Statement

Plaintiff Suffolk County (the “County” or “Suffolk”) alleges that defendants<sup>1</sup> have caused New York State to overpay for Medicaid drugs and that the County, which is billed for a share of the State’s expenditures, has thus overpaid as well. First, plaintiff contends that the State pays retail pharmacists too much because the reimbursement formula for prescriptions they fill is based in part on drugs’ “average wholesale price” (“AWP”) as reflected in trade publications and defendants allegedly have fraudulently inflated those AWP’s. Second, plaintiff contends that defendants have misreported to the federal Secretary of Health and Human Services (the “Secretary”) prices that form the basis of “rebates” paid by defendants to New York (and other states) pursuant to the Medicaid statute and defendants’ contracts with the Secretary (“Rebate Agreements”).

Suffolk admits that it has no input into the process by which the State determines how much it will pay for Medicaid drugs. At best, the County is an “indirect purchaser” of Medicaid drugs -- one of a total of 58 counties in the State of New York. Suffolk’s injury, if any, is entirely derivative of that of the State.

New York State has already sued certain of the defendants in this case making allegations similar to those made here. Those cases are presently before this Court. Suffolk does not have independent standing to sue; if it did, there would be a serious risk of double recoveries and inconsistent judgments.

Even if Suffolk had standing to sue, however, its AWP claims should be dismissed. First, the County’s RICO claims are virtually identical to those alleged in the Master

Consolidated Complaint, which have already been dismissed, and in the Amended Master Consolidated Complaint, which (defendants submit) should also be dismissed. Second, it is undisputed that New York *knows* that AWP's do not represent pharmacists' actual acquisition costs of Medicaid drugs; indeed, that is why the State reimburses under Medicaid at AWP *minus* 12%. Suffolk's complaint is that the discount should be even greater. Suffolk does not allege that defendants have in any way interfered with New York's setting of the discount. Under the circumstances, therefore, there is no basis for a claim of fraud.

Suffolk's rebate claims are both procedurally and substantively flawed, as well. The federal rebate statute and the defendants' Rebate Agreements with the Secretary under which the County sues do not give the *states*, let alone a political subdivision of a state, a private right of action. To the extent that Suffolk instead seeks to sue defendants for violation of the rebate statute or Rebate Agreements under New York state law, those claims are preempted by federal law. Moreover, Suffolk's claim that defendants have misreported their prices to the Secretary is totally devoid of any particulars. Rather, plaintiff baldly claims that its "initial research" indicates that misreporting is "pervasive" in the industry. (Am. Compl. ¶ 13.) This is not sufficient under Fed. R. Civ. P. 9(b).

In short, Suffolk County is not a proper party and its claims of AWP fraud and rebate misreporting are not only insufficiently pled but are belied by the Amended Complaint itself. The case should be dismissed.

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<sup>1</sup> Only those defendant companies upon whom plaintiff has effected service join in the instant motion to dismiss. Suffolk has not effected service upon Bayer AG and Immunex and thus neither company joins in the instant motion.

### Factual Background<sup>2</sup>

#### *The Federal Medicaid Program And The States' Roles Generally*

Medicaid is a “grant-in-aid” program in which the federal government reimburses states for a substantial portion of the costs incurred by them in providing medical assistance to qualifying low-income persons. *See* 42 U.S.C. § 1396 *et seq.* (2003). All 50 states have Medicaid programs that provide a prescription drug benefit.<sup>3</sup> In contrast to the Medicare program, which covers only limited categories of drugs, Medicaid drug benefits generally include most prescription drugs dispensed at retail pharmacies, as well as drugs administered by physicians. Furthermore, while “Average Wholesale Price”, or “AWP”, is a term that appears (albeit undefined) in the federal Medicare statute, it does not appear in the federal Medicaid statute. Indeed, the federal agency responsible for Medicaid, the Center for Medicare and Medicaid Services (“CMS”), formerly known as the Health Care Financing Administration, or “HCFA”, has repeatedly warned states not to rely on AWP in determining reimbursement rates for prescription drugs. *See Louisiana v. Dep’t of Health & Human Servs.*, 905 F.2d 877, 880 (5th Cir. 1990).

Under Federal law, state Medicaid agencies may not pay more for prescribed drugs than the limits imposed by CMS. 42 C.F.R. § 447.333(b)(2) (2003). For certain “multiple source” drugs, the federal government will reimburse the states no more than a reasonable dispensing fee plus an amount that is 150% of the published price for the *least* costly therapeutic

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<sup>2</sup> For the Court’s convenience, some of the regulations, administrative interpretations and other public documents mentioned in this fact section are included in the Appendix submitted herewith. Citations to the Appendix appear as “Defs. App. Ex. \_\_\_\_.”

<sup>3</sup> *See* Medicaid Prescription Reimbursement Information by State - Qtr Ending June 2003, available at <http://www.cms.hhs.gov/medicaid/drugs/prescriptions.asp> (last visited September 14, 2003).

equivalent that can be purchased by pharmacists in standard quantities (*e.g.*, 100 tablet amounts). 42 C.F.R. § 447.332(b) (2003). For all other drugs, *i.e.*, single source drugs or multiple source drugs for which no upper limit has been established, the state may pay the *lower* of the “[e]stimated acquisition cost” or “EAC” of the drug (plus a reasonable dispensing fee as established by the state Medicaid agency) or the providers’ usual and customary charges to the general public. 42 C.F.R. § 447.331(b) (2003). EAC is defined as the state Medicaid agency’s “best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers.” 42 C.F.R. § 447.301 (2003).

Although federal EAC regulations do not require a state to ascertain precisely a Medicaid provider’s *actual* acquisition cost for a drug, the “intent of [the final Medicaid] regulations on drug reimbursement is to have each state’s estimated acquisition cost as close as feasible to the price generally and currently paid by the provider.” Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC), HFCA Action Transmittal No. 77-13 (MMB), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 28,714 (Dec. 13, 1977) (Defs. App. Ex. A).<sup>4</sup> HCFA has encouraged each state’s “program

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<sup>4</sup> In 1974, the Department of Health, Education, and Welfare (“HEW”) explained that it intended to discontinue the use of AWP as a benchmark for Medicaid drug payment because AWP’s “are frequently in excess of actual acquisition cost to the retail pharmacist.” Proposed Reimbursement of Drug Cost, 39 Fed. Reg. 41,480 (Nov. 27, 1974) (Defs. App. Ex. B). Instead, “to achieve maximum savings to the Medicaid program,” the agency initially proposed to forego AWP in favor of “actual acquisition cost” (“AAC”). *Id.* In comments on the proposed rule, many pharmacists requested that the agency let state Medicaid agencies continue to reimburse based on AWP as a means of boosting “pharmacy income.” Limits on Payments for Drugs, 40 Fed. Reg. 34,516, 34,518 (Aug. 15, 1975) (Defs. App. Ex. C). HEW rejected the pharmacists’ request because “AWP data are frequently inflated. The purpose of the proposed regulations [based on AAC] was to achieve savings. The final regulations [based on EAC] have been

administrator [to] re-evaluate the state's method of setting EAC limits for the [state's Medicaid] drug program to assure that drug reimbursement limits are as close as feasible to Actual Acquisition Cost." *Id.*<sup>5</sup>

Since issuing the final Medicaid regulations, HCFA has regularly warned the states *not* to rely on AWP as a proxy for EAC. As HHS's Office of Inspector General ("HHS OIG") noted, "[w]ithin the pharmaceutical industry, AWP means *non-discounted list price*. Pharmacies [actually] purchase drugs at prices that are *discounted significantly* below AWP or list price." Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs, Medicaid Transmittal No. 84-12, *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 34,157, at 10,193 (Sept. 1984) (Defs. App. Ex. D) (emphasis added). That HHS OIG report continued:

[P]harmacies do not purchase drugs at the AWP published in the "Bluebook," "Redbook" or other similar publications. Thus, AWP cannot be the best -- or even an adequate -- estimate of the prices providers generally are paying for drugs. AWP represents the list price and often does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates or free goods that do not appear on the pharmacists' invoices.

*Id.* at 10,206.<sup>6</sup>

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modified to take into account some of the administrative problems of States in determining AAC." *Id.*

<sup>5</sup> As discussed below, New York has decided to reimburse *certain* drugs only at the Medicaid provider's actual acquisition cost. This shows that New York knows how to limit reimbursement to actual cost when it wishes to do so.

<sup>6</sup> HHS issued a similar report in 1989. *See* HHS OIG Report, "Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program", A-06-89-00037 (Oct. 1989), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 38,215 (1990) (Defs. App. Ex. E).

When HHS issued a revision to the State Medicaid Manual in 1989, it disapproved the proposed Medicaid plans of states that used undiscounted AWP (*i.e.*, 100% of AWP) as the proxy for the statutory EAC drug reimbursement rate, and in several cases HCFA refused to pay the states the federal share of Medicaid drug dollars because of the states' reliance on AWP. *See Louisiana v. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990); *In re Arkansas Dep't of Human Servs.*, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991); *In re Oklahoma Dep't of Human Servs.*, 1991 WL 634860 (HHS Dept. App. Bd. Aug. 13, 1991).<sup>7</sup> *See also Rite Aid of Pa., Inc. v. Houstoun*, 171 F.3d 842, 847 (3d Cir. 1999) (noting that "[t]he HCFA informed [Pennsylvania] that it would not accept AWP levels for 'EAC without a significant discount being applied,' unless the [State] provided documentation that the actual acquisition cost equaled the full AWP.").

*The "Best Price" Provisions – Rebates For The Government Payors*

Congress took action in 1990 to reform the Medicaid scheme. It placed a four-year moratorium on changes to states' reimbursement methodologies, *see* Omnibus Budget Reconciliation Act of 1990, as amended, codified at 42 U.S.C. § 1396r-8(e), and adopted the Medicaid rebate statute. 42 U.S.C. § 1396r-8 (2003); *see Nebraska Pharmacists Assoc. v. Nebraska Dep't of Soc. Servs.*, 863 F. Supp. 1037, 1043 (D. Neb. 1994) (discussing Congressional actions). The rebate statute authorized drug manufacturers to enter into contracts with CMS to pay rebates to the states on Medicaid drugs, the goal being to reduce the federal

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<sup>7</sup> In the *Louisiana* case, the federal government filed a brief stating that "AWP has become like the 'sticker price on an automobile. It is the *very highest price* that anyone would be expected to pay for a drug product.'" Brief of Respondent at 23 n.9, *Louisiana v. U.S. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. Jan. 12, 1990) (No. 89-4566) (Defs. App. Ex. F) (emphasis added). The Fifth Circuit agreed and concluded that HCFA had properly prohibited the state from using AWP as the basis for EAC. *Id.* at 877.

government's and the states' Medicaid drug expenditures below providers' EAC (however defined by the states) and to parallel more closely the after-discount amounts paid by the manufacturers' favored commercial buyers. 42 U.S.C. § 1396r-8(b)(1)(A) (2003).

Under the rebate statute, states are required to include in their Medicaid plans drugs from those manufacturers that enter into a formal rebate agreement with HCFA/CMS (the "Rebate Agreement"). A Rebate Agreement requires the manufacturer to submit to the federal government the "average manufacturer price" ("AMP") for each of its drugs and the "best price" ("BP") at which the drugs are sold. 42 U.S.C. § 1396r-8(b)(3)(A)(i) (2003). Both of these terms, unlike AWP, are defined by federal statute.<sup>8</sup> CMS imports data on AMP and BP into a statutory formula to compute a quarterly unit rebate amount. Upon receipt of the unit amounts, the states multiply the figures by the Medicaid quantities or "utilization" of the respective drugs for the quarter in question and bill the manufacturers accordingly. 42 U.S.C. § 1396r-8(b)(2)(A) (2003). Under federal law, CMS may share with the states the unit rebate amount, but not the underlying data relating to AMP and BP. 42 U.S.C. § 1396r-8(b)(3)(D) (2003); form Rebate Agreement, Section VII. However, the states can derive some of this price data themselves or call for it under state programs.<sup>9</sup>

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<sup>8</sup> "Average manufacturer price" is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-8(k)(1) (2003). "Best price" is defined as "the lowest price available from the manufacturer . . . to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States . . ." 42 U.S.C. § 1396r-8(c)(1)(C) (2003). The form Rebate Agreement appears in the Federal Register. "Medicaid Program; Drug Rebate Agreement," 56 FR 7049, 7050 (Feb. 21, 1991) (Defs. App. Ex. G), *also available at* <http://www.cms.gov/medicaid/drugs/rebate.pdf> (Defs. App. Ex. H).

<sup>9</sup> For example, although CMS does not give AMP data to States, the exact AMP or, in some cases, the maximum AMP can easily be calculated by the states. For non-innovator multiple-

Under the rebate statute and the Rebate Agreements, the federal government has authority to audit the price reporting of the drug manufacturers. 42 U.S.C. § 1396r-8(b)(3)(D); form Rebate Agreement, Section V(d). The statute provides penalties and procedures for misreporting of prices by the manufacturers. Manufacturers have the right to challenge a state's utilization figures through an alternative dispute resolution process. The states' role in disputes over rebate amounts is limited to resolution of discrepancies in the "utilization" figures they provide to the manufacturers; the states have no role in disputes over manufacturers' price reporting. The Secretary of HHS is the sole enforcer on this issue.<sup>10</sup>

*Continuing Review of EAC and AWP*

Notwithstanding the advent of the rebate statute and agreements, HHS has continued to press states to revise how they pay Medicaid providers for drugs in the first instance. In 1995, HCFA requested HHS OIG to investigate the disparities between AWP and actual pharmacy acquisition costs for EAC purposes. HHS OIG initially picked 11 states at random and, based on its research, estimated in 1996 and 1997 that AWP exceeded invoice prices for "brand name" drugs by an average of 18.3 % and for "generic" drugs by an average of

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source drugs, the per-unit rebate is simply 11% of AMP. 42 U.S.C. § 1396r-8(c)(3) (2003). For single-source and innovator drugs, the minimum per-unit rebate the states receive is 15% of AMP. In either case, the states need only divide the per-unit rebate by 11% or 15% to determine exact or maximum AMP. New York is also able to obtain price discovery directly from manufacturers under its own statutes. *See infra*, at 12 (*citing* N.Y. Soc. Serv. Law § 367-a(7)).

<sup>10</sup> As discussed in further detail below, under Section 1396r-8(b)(3)(C)(i), a manufacturer who fails to provide information on a timely basis is subject to a penalty, the amount of which shall be increased by \$10,000 for each day in which such information is not provided. If a manufacturer knowingly provides false information, it must pay an amount not to exceed \$100,000 for each item of false information. 42 U.S.C. § 1396r-8(b)(3)(C)(ii). The Secretary of HHS is also authorized to terminate a manufacturer's rebate agreement "for violation of the requirements of the agreement or other good cause shown." 42 U.S.C. 1396r-8(b)(4)(B)(i).